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BROOKS KUSHMAN P.C.
1000 TOWN CENTER
TWENTY-SECOND FLOOR
SOUTHFIELD, MI 48075

EXAMINER

RINES, ROBERT D

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PAPER

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1 UNITED STATES PATENT AND TRADEMARK OFFICE

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4 BEFORE THE BOARD OF PATENT APPEALS
5 AND INTERFERENCES
6

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8 *Ex parte* JOHN M. FLACK and LOWELL A. HEDQUIST
9

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11 Appeal 2009-006761
12 Application 10/036,202
13 Technology Center 3600
14

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16 Decided: December 28, 2009
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19 Before MURRIEL E. CRAWFORD, ANTON W. FETTING, and JOSEPH
20 A. FISCHETTI, *Administrative Patent Judges*.
21 FETTING, *Administrative Patent Judge*.

22 DECISION ON APPEAL
23

1 STATEMENT OF THE CASE

2 John M. Flack and Lowell A. Hedquist (Appellants) seek review under
3 35 U.S.C. § 134 (2002) of a final rejection of claims 1-19, the only claims
4 pending in the application on appeal.

5 We have jurisdiction over the appeal pursuant to 35 U.S.C. § 6(b)
6 (2002).

7 SUMMARY OF DECISION¹

8 We AFFIRM.

9 THE INVENTION

10 The Appellants invented a patient healthcare management methods and
11 systems having the capability to evaluate patient kidney function
12 (Specification 1:6-9).

13 An understanding of the invention can be derived from a reading of
14 exemplary claims 1, 10, and 18, which are reproduced below [bracketed
15 matter and some paragraphing added].

¹ Our decision will make reference to the Appellants' Appeal Brief ("App. Br.," filed July 14, 2008) and Reply Brief ("Reply Br.," filed November 26, 2008), and the Examiner's Answer ("Ans.," mailed October 1, 2008), and Final Rejection ("Final Rej.," mailed February 11, 2008).

1 1. A patient healthcare management system having a capability
2 to evaluate patient kidney function, the system configured to:
3 [1] receive input defining a patient's medical record
4 including the patient's demographic information, medical
5 condition and diagnosis;
6 [2] calculate the patient's estimated glomerular filtration rate
7 based on the patient's medical record;
8 [3] output at least one medical treatment recommendation
9 wherein the recommendation is based on the patient's medical
10 record and estimated glomerular filtration rate; and
11 [4] calculate and output at least one treatment goal for the
12 patient.

13

14 10. A computer-implemented patient healthcare management
15 method involving the evaluation of patient kidney function, the
16 method comprising:

17 [1] defining a patient's medical record including the patient's
18 demographic information, medical condition and diagnosis;
19 [2] calculating the patient's estimated glomerular filtration
20 rate based on the patient's medical record;
21 [3] automatically generating at least one medical treatment
22 recommendation based on the patient's medical record and
23 estimated glomerular filtration rate; and
24 [4] calculating at least one treatment goal for the patient.

25

26 19. A computer-based system for interactively managing
27 patient healthcare and evaluating patient kidney function, the
28 system comprising:

29 [1] a means for defining a patient's medical record;
30 [2] a means for establishing the patient's estimated
31 glomerular filtration rate based on the patient's medical record;

- 1 [3] a means for generating at least one patient treatment
2 recommendation based on the patient's medical record and
3 estimated glomerular filtration rate; and
4 [4] a means for calculating at least one treatment goal for the
5 patient.

6

7 THE REJECTIONS

8 The Examiner relies upon the following prior art:

Tannenbaum	US 2003/0019115 A1	Jan. 30, 2003
Pestotnik et al.	US 2004/0260666 A1	Dec. 23, 2004

9

10 Claims 10-18 stand rejected under 35 U.S.C. § 101 as being directed
11 toward non-statutory subject matter.

12 Claims 1-19 stand rejected under 35 U.S.C. § 103(a) as unpatentable
13 over Pestotnik and Tannenbaum.

14

15 ISSUES

16 The issues pertinent to this appeal are:

- 17 • Whether the Appellants have sustained the burden of showing that the
18 Examiner erred in rejecting claims 10-18 under 35 U.S.C. 101 as
19 being directed towards non-statutory subject matter.
- 20 ○ This pertinent issue turns on whether claims 10-18 recited a
21 process that is patent-eligible under the machine-or-
22 transformation test.

- 1 • Whether the Appellants have sustained the burden of showing that the
2 Examiner erred in rejecting claims 1-19 under 35 U.S.C. § 103 as
3 unpatentable over Pestotnik and Tannenbaum.
 - 4 ○ This pertinent issue turns on whether Pestotnik describes a
5 system configured to calculate and output at least one treatment
6 goal for the patient, as required by limitation [4] of claim 1 and
7 Tannenbaum describes using the medical record of a patient in
8 determining the patient's glomerular filtration rate.

10 FACTS PERTINENT TO THE ISSUES

11 The following enumerated Findings of Fact (FF) are believed to be
12 supported by a preponderance of the evidence.

13 *Facts Related to Appellants' Disclosure*

- 14 01. A calculator extracts patient information to calculate the
15 patient's glomerular filtration rate (Specification 22:13-15).
16 Equations to calculate a patient's glomerular filtration rate
17 incorporate the patient's height, weight, and age (Specification
18 22:20-24).

19 *Facts Related to the Prior Art*

20 *Pestotnik*

- 21 02. Pestotnik is directed to a decision-support system where
22 information is analyzed to provide an individual with one or more
23 suggested recommendations (Pestotnik ¶ 0003). Pestotnik is

1 concerned with creating an expert system that allows for the
2 evaluation of a patient without the need to re-input patient data
3 each time the patient is examined (Pestotnik ¶ 0011).

4 03. The method includes presenting a patient with questions,
5 gathering data from the patient, and evaluating the patient data to
6 determine a diagnosis and medical care recommendations for the
7 patient's medical condition (Pestotnik abstract). Clinicians are
8 provided with patent specific data and are provided with a medical
9 diagnosis and a medical care recommendation that is based upon a
10 large expert knowledge base (Pestotnik ¶ 0022).

11 04. A clinician may request that the progress note module
12 summarize patient data, which contains the pertinent information
13 to the medical condition of the patient (Pestotnik ¶ 0094).
14 Following the data collection, the decision support module
15 generates a recommendation for treatment of the patient, based on
16 the patient data, microbial susceptibilities, and the patient family
17 history (Pestotnik ¶'s 0138 and 0174). The system may further
18 include an analysis for the need for a referral, other tests,
19 microbial susceptibility or genetic predispositions to the disease or
20 medical condition, family history, behavioral and lifestyle
21 changes, and patient education (Pestotnik ¶'s 0140 and 0174).

22 05. After determining the cause of a medical condition, the system
23 gathers any susceptibilities and any mitigating factors (Pestotnik ¶
24 0150). Each mitigating factor may include a rule stored in the
25 knowledge module that may be used to guide the decision-support

1 process of the present invention (Pestotnik ¶ 0150). The decision-
2 support module then generates updated patient data and an
3 updated progress note with a ranked list of recommendations
4 (Pestotnik ¶ 0151).

5 *Tannenbaum*

6 06. Tannenbaum is directed to a device for establishing renal
7 function by utilizing blood serum creatinine level in combination
8 with body weight, sex, and age to calculate a patient's glomerular
9 filtration rate (Tannenbaum ¶ 0001).

10 07. The device comprises a hand-held precision sliding ruler
11 instrument designed to provide an indication of renal function by
12 utilizing a measurement of a patient's serum creatinine level in
13 combination with body weight, sex, and age (Tannenbaum ¶
14 0014).

15 *Facts Related To The Level Of Skill In The Art*

16 08. Neither the Examiner nor the Appellants has addressed the level
17 of ordinary skill in the pertinent art of patient healthcare
18 management systems. We will therefore consider the cited prior
19 art as representative of the level of ordinary skill in the art. *See*
20 *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001)
21 (“[T]he absence of specific findings on the level of skill in the art
22 does not give rise to reversible error ‘where the prior art itself
23 reflects an appropriate level and a need for testimony is not
24 shown’”) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys.*
25 *Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985).

Facts Related To Secondary Considerations

09. There is no evidence on record of secondary considerations of non-obviousness for our consideration.

PRINCIPLES OF LAW

101 - Bilski

The law in the area of patent-eligible subject matter for process claims has recently been clarified by the Federal Circuit in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), *petition for cert. filed*, 77 USLW 3442 (U.S. Jan. 28, 2009) (No. 08-964).

The en banc court in *Bilski* held that “the machine-or-transformation test, properly applied, is the governing test for determining patent eligibility of a process under § 101.” *Id.* at 956. The court in *Bilski* further held that “the ‘useful, concrete and tangible result’ inquiry is inadequate [to determine whether a claim is patent-eligible under § 101.]” *Id.* at 959-60.

The court explained the machine-or-transformation test as follows: “A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.” *Id.* at 954 (citations omitted). The court explained that “the use of a specific machine or transformation of an article must impose meaningful limits on the claim’s scope to impart patent-eligibility” and “the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity.” *Id.* at 961-62 (citations omitted).

1 The court declined to decide under the machine implementation branch
2 of the inquiry whether or when recitation of a computer suffices to tie a
3 process claim to a particular machine. *Id.* at 962. As to the transformation
4 branch of the inquiry, however, the court explained that transformation of
5 a particular article into a different state or thing “must be central to the
6 purpose of the claimed process.” *Id.* As to the meaning of “article,” the
7 court explained that chemical or physical transformation of physical objects
8 or substances is patent-eligible under § 101. *Id.* The court also explained
9 that transformation of data is sufficient to render a process patent-eligible if
10 the data represents physical and tangible objects, i.e., transformation of such
11 raw data into a particular visual depiction of a physical object on a display.
12 *Id.* at 962-63. The court further noted that transformation of data is
13 insufficient to render a process patent-eligible if the data does not specify
14 any particular type or nature of data and does not specify how or where the
15 data was obtained or what the data represented. *Id.* at 962 (citing *In re*
16 *Abele*, 684 F.2d 902, 909 (CCPA 1982) (process claim of graphically
17 displaying variances of data from average values is not patent-eligible) and
18 *In re Meyer*, 688 F.2d 789, 792-93 (CCPA 1982) (process claim involving
19 undefined “complex system” and indeterminate “factors” drawn from
20 unspecified “testing” is not patent-eligible)).

21
22 *Obviousness*

23 A claimed invention is unpatentable if the differences between it and
24 the prior art are “such that the subject matter as a whole would have been
25 obvious at the time the invention was made to a person having ordinary skill

1 in the art.” 35 U.S.C. § 103(a) (2000); *KSR Int’l Co. v. Teleflex Inc.*, 550
2 U.S. 398, 406 (2007); *Graham v. John Deere Co.*, 383 U.S. 1, 13-14 (1966).

3 In *Graham*, the Court held that that the obviousness analysis is
4 bottomed on several basic factual inquiries: “[(1)] the scope and content of
5 the prior art are to be determined; [(2)] differences between the prior art and
6 the claims at issue are to be ascertained; and [(3)] the level of ordinary skill
7 in the pertinent art resolved.” 383 U.S. at 17. *See also KSR*, 550 U.S. at
8 406. “The combination of familiar elements according to known methods is
9 likely to be obvious when it does no more than yield predictable results.” *Id.*
10 at 416.

11 ANALYSIS

12 *Claims 10-18 rejected under 35 U.S.C. § 101 as being directed toward*
13 *non-statutory subject matter*

14 The Appellants contend that claims 10-18 recite the transformation of
15 data, where the patient’s demographic information, medical condition, and
16 diagnosis are transformed into a medical treatment recommendation (Reply
17 Br. 4). The Appellants argue that this transformation is parallel to the data
18 held patent-eligible in *Abele* and is therefore sufficient to render claims 10-
19 18 of the claimed invention patent-eligible (Reply Br. 4).

20 We disagree with the Appellants. The second prong of the machine-or-
21 transformation test articulated in *Bilski* requires a process that transforms a
22 particular article into a different state or thing. The court also explained that
23 transformation of data is sufficient to render a process patent-eligible if the
24 data represents physical and tangible objects and is insufficient if the data

1 does not specify any particular type or nature of data and does not specify
2 how or where the data was obtained or what the data represented.

3 The steps of process claims 10-18 fail the second prong of the machine-
4 or-transformation test because the data processed in the claims do not
5 represent physical and tangible objects. The data recited in claims 10-18
6 represent demographic information, medical condition information, and
7 diagnosis information, which are not physical and tangible objects. The
8 Appellants argue that these data elements represent a medical record,
9 however, these are merely information that may be included in a medical
10 record. Furthermore, a medical record, such as an electronic medical record,
11 may not necessarily be a physical and tangible object. The data in *Abele* is
12 distinguished because that data represents measured physical and tangible
13 characteristics of objects such as bones, organs, and other body tissue. The
14 data in the claimed invention is not directed to any physical and tangible
15 object and therefore is not patent-eligible.

16 Additionally, claims 10-18 fail the first prong of the machine-or-
17 transformation test. The Appellants have not contested that claims 10-18
18 satisfy the machine prong of the machine-or-transformation test and we find
19 that claims 10-18 fail to recite a process that is tied to a particular machine
20 or apparatus.

21 As such, claims 10-18 fail to satisfy the both prongs of the machine-or-
22 transformation test and are rejected under 35 U.S.C. § 101 as being directed
23 towards non-statutory subject matter.

24

1 *Claims 1-19 rejected under 35 U.S.C. § 103(a) as unpatentable over*
2 *Pestotnik and Tannenbaum*

3 The Appellants first contend that (1) Pestotnik fails to describe a system
4 configured to calculate and output at least one treatment goal for the patient,
5 as required by limitation [4] of claim 1 (App. Br. 3). The Appellants
6 specifically argue that Pestotnik is only configured to use “rules” to generate
7 medical diagnoses and patient care recommendations (App. Br. 5). We
8 disagree with the Appellants. Pestotnik describes a decision support system
9 that collects patient data and determines a proper course of action for the
10 patient (FF 02 and FF 03). Pestotnik specifically describes that data from
11 the patient is first collected (FF 03) and then the decision-support module
12 generates a recommendation for treatment of the patient (FF 04). The
13 treatment plan for the patient is based on the patient data, microbial
14 susceptibilities, and the patient family history (FF 04). The treatment plan
15 generated by Pestotnik is a treatment goal for the patient, as required by
16 the claimed invention. As such, Pestotnik describes that the rules further
17 generate a treatment plan beyond a diagnosis and recommendation and
18 therefore Pestotnik describes limitation [4] of claim 1.

19 The Appellants also contend that (2) there is no reason to combine
20 Pestotnik and Tannenbaum since Pestotnik does not have the capability of
21 being combined with a hand held calculator (App. Br. 6). We disagree
22 with the Appellants. Pestotnik is concerned with providing a system that
23 evaluates a patient based on collected patient data (FF 02). Pestotnik
24 accomplishes this goal by providing a system that provides clinicians with a
25 medical diagnosis, a medical care recommendation, and a medical treatment
26 plan based on specific patient data (FF 03 and FF 04). Tannenbaum is also

1 concerned with providing an evaluation and diagnosis of a patient (FF 06).
2 Tannenbaum accomplishes this goal by providing a device for calculating a
3 patient's glomerular filtration rate that includes a hand-held precision sliding
4 ruler instrument designed to provide an indication of renal function by
5 utilizing a measurement of a patient's serum creatinine level in combination
6 with body weight, sex, and age (FF 07).

7 A person with ordinary skill in the art would have recognized that a
8 medical diagnosis device (as described by Tannenbaum) can be seamlessly
9 used with a system that evaluates information and further provides a
10 diagnosis and decision support (as described by Pestotnik). That is, a system
11 that performs a specific function in evaluating patient data can incorporate a
12 device that collects specific patient data to be used for that evaluation. A
13 person with ordinary skill in the art would have recognized that the use of
14 the device described by Tannenbaum with the system described Pestotnik
15 would yield predictable results. As such, a person with ordinary skill in the
16 art would have been lead to combine Pestotnik and Tannenbaum at the time
17 of the claimed invention.

18 The Appellants further contend that (3) Tannenbaum fails to describe a
19 means for establishing a patient's estimated glomerular filtration rate based
20 on a patient's medical record, as per claim 19 (App. Br. 7). We disagree
21 with the Appellants. The Specification discloses that a calculator can be a
22 means for calculating a patient's glomerular filtration rate based on the
23 patient's medical record (FF 01). Tannenbaum describes a device for
24 calculating a patient's glomerular filtration rate that includes a hand-held
25 precision sliding ruler instrument designed to provide an indication of renal
26 function by utilizing a measurement of a patient's serum creatinine level *in*

1 *combination with body weight, sex, and age* (FF 07). That is, Tannenbaum
2 describes a device that acts as a calculator that utilizes information in the
3 patient medical record in combination with the described device to
4 determine the patient's glomerular filtration rate. The Appellants further
5 point to equations 1 and 2 from the specification that describes the use of
6 medical record information in estimating the glomerular filtration rate (App.
7 Br. 7). It is clear from these disclosed equations that the claimed invention
8 and Tannenbaum both use the same patient information of *body weight* and
9 *age* from the patient's medical record is used to determine the patient's
10 glomerular filtration rate (FF 01). As such, Tannenbaum does use the
11 medical record of the patient in combination with the described device in
12 determining the patient's glomerular filtration rate.

13 The Appellants additionally contend that Pestotnik fails to describe a
14 system configured to calculate and output at least one treatment goal for the
15 patient as required by claim 19 and as argued *supra* in support of claim 1.
16 This argument was not found persuasive *supra* and is not found persuasive
17 here for the same reasons.

18 The Appellants have not sustained the burden of showing that the
19 Examiner erred in rejecting claims 1-19 under 35 U.S.C. § 103(a) as
20 unpatentable over Pestotnik and Tannenbaum.

21
22 CONCLUSIONS OF LAW

23 The Appellants have not sustained the burden of showing that the
24 Examiner erred in rejecting claims 10-18 under 35 U.S.C. § 101 as being
25 directed towards non-statutory subject matter.

1 The Appellants have not sustained the burden of showing that the
2 Examiner erred in rejecting claims 1-19 under 35 U.S.C. § 103(a) as
3 unpatentable over Pestotnik and Tannenbaum.

4

5

DECISION

6

To summarize, our decision is as follows.

7

- The rejection of claims 10-18 under 35 U.S.C. § 101 as being directed
8 towards non-statutory subject matter is sustained.

9

- The rejection of claims 1-19 under 35 U.S.C. § 103(a) as unpatentable
10 over Pestotnik and Tannenbaum is sustained.

11

No time period for taking any subsequent action in connection with this
12 appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2007).

13

AFFIRMED

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JRG

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BROOKS KUSHMAN P.C.

22

1000 TOWN CENTER

23

TWENTY-SECOND FLOOR

24

SOUTHFIELD, MI 48075